

10/549914

1 JC17 Rec'd PCT/PTO 20 SEP 2005

[Translation]

REPLY

To: Yumiko Kawaguchi, Examiner of the Patent Office

1. Identification of the International Application PCT/JP2004/004319

2. Applicant

Name: Cheiron Japan Co.

Address: 202, 25-1, Funabashi 3-chome, Setagaya-ku, Tokyo, 156-0055 Japan

Country of nationality: JAPAN

Country of residence: JAPAN

3. AGENT

Name: (8127) Yoshiharu Yoshida, Patent Attorney

Address: Shuwa No.2 Toranomom Building 6F, 21-19, Toranomom 1-chome,
Minato-ku, Tokyo, 105-0001 Japan

4. Date of Notification: 01.06.2004

5. Subject Matter of Reply

(a) Progress Record

The PCT written opinion indicates that Claims 1, 5 and 9 lack novelty and inventive step and Claims 1-3 and 5-10 lack inventive step. The opinion relies on the following documents D1-D6.

The applicant would respectfully argue against the official opinions as follows and submit an amendment as per attached.

<References cited>

Citation 1: Bliss DZ et al., Am J Clin Nutr., Mar.1996; 63(3), pp.392-398

Citation 2: Hassan Y et al., J Nutr Biochem., 1998; 9(11); pp.613-620

Citation 3: JP 2-289520(A)

Citation 4: JP 6-256197(A)

Citation 5: JP 6-22725(A)

Citation 6: JP 63-135334(A)

(b) Contents and Explanation of Amendment

Claim 1 is amended to "Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds, which contains, as basic ingredients, more than 5% by weight of water-soluble indigestible polysaccharides exploited by intestinal bacteria in terms of dried foodstuff and has restricted addition of protein components."

The amendment as noted above is relied on the description "by administering indigestible polysaccharides as food having energy required for protein synthesis by bacteria, which is difficult to digest according to digestive enzyme and may be ingested as food according to intestinal bacteria" in the specification on file (page 5, lines 9-11), and the description "these enterobacteria can easily take in water-soluble dietary fiber (pectine, gum, oligosaccharide, alginic acid, chitosan, etc.)" (page 5, lines 25-26).

The phrase "5% by weight ... in terms of dried foodstuff" in Claim 1 is relied on the original Claim 2.

Also, Claim 2 is amended to "Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to Claim 1, wherein said food contains more than 5% by weight of indigestible polysaccharides in terms of dried foodstuff and protein components restricted to 8% or less by weight." This amendment of Claim 2 is predicated on the inclusion of the subject matter of Claim 2 in part into Claim 1.

(c) Characteristic Features of the Invention

As set forth in Claim 1, the "pathological improvement food" according to the present invention is featured by containing more than 5% by weight of water-soluble indigestible polysaccharides exploited by intestinal bacteria in terms of dried foodstuff and restricting addition of protein components. This feature of the invention makes it possible to "decrease the amount of nitrogen reabsorbed from the intestine into the bloodstream ... the low-molecular-weight nitrogen-containing compounds such as urea discharged from the blood (through the blood vessel) into the intestine are effected for protein synthesis of intestinal bacteria and passed out with feces" (see page 10, lines 2-5 in the specification on file). As a result, the pathological improvement food of the invention brings about the effects: (1) The blood concentration of the

nitrogen-containing low-molecular substances such as BUN and ammonia can be lowered. (2) It becomes possible to alleviate the burdens exerted on the kidney of a kidney failure patient and retard a transition to hemodialysis treatment only by taking a specified quantity of the food of the invention every day. (3) The number of required hemodialysis required for treating kidney failure can be decreased to lessen the psychological, temporal and financial burdens upon the patient and heighten the quality of life of the patient while saving medical expenses. (4) The blood ammonia level can be decreased so as to keep a patient with acute or chronic hepatic failure from a danger of falling into hepatic coma and improve the medical condition of the patient. (See page 22, lines 4-11)

(d) Comparison with the conventional related arts

Citation 1 mentions that the concentration of serum urea nitrogen is decreased by administering liquid added with gum arabic (lines 4-8 on the right column of page 395). Citation 2 mentions that plasma urea concentration is least decreased in case of the food having low casein concentration and containing dietary fiber (lines 3-8 on the left column of page 616).

The Examiner has deemed the invention set forth in Claim 1 to lack novelty and inventive step over the Citations 1 and 2.

However, as seen from the description "Group A supplemented their usual LPD with 25g gum Arabic ... in 150mL juice twice daily ... for 4 wk" (lines 47-49 on the left column of page 393), Citation 1 provides a "tentative" technology, not food, merely demonstrating an analysis result of the administration of liquid containing gum arabic. Meanwhile, the present invention provides a beneficial technology to identify the contents of indigestible polysaccharides contained in food as the chief ingredients in view of possibility and eating texture and further restricting addition of protein component so as to take even solely in producing the food in the form of biscuits or the like. However, Citation merely discloses the effectiveness of gum arabic for chronic renal disease, but does not take consideration of the contents and relative balance of various components for use in pathological improvement food. The applicant believes that the present invention could not be inferred from Citation 1.

Citation 2 mentions that "The purpose of this study was to determine the effect of an indigestible carbohydrate/dietary fiber ... on extra-renal nitrogen in nephrectomized

rats." (See lines 1 -2 of Abstract) Thus, this citation is featured by using rats, which are compulsorily made into the state of acute renal failure by nephrectomy. Such acute conditions will be caused only in singular circumstances such as a traffic accident in a human environment. Thus, the medical subject of the cited art is essentially distinct from that of the present invention. The applicant believe that the present invention could not be inferred from Citation 2.

Further, Citation 2 makes use of insoluble fiber such as insoluble oat fiber, soy polysaccharide and carboxymethylcellulose in addition to soluble indigestible polysaccharides (soluble fiber) exploited by intestinal bacteria such as gum arabic (see Abstract of the citation). However, such insoluble fiber is not exploited by the intestinal bacteria and excreted from the body as it is. Therefore, the effect of lowering the blood concentration of nitrogen-containing low-molecular compounds as brought about by the present invention can in no way be produced by Citation 2. Besides, substances (41.2% fructooligosaccharides and 10.3% gum arabic), which are equated with the soluble indigestible polysaccharide as seen in the present invention, exist only 4% of the total quantity in the light of 8% of fiber contained therein (see Abstract of the citation), thus resulting in insufficient consumption of nitrogen-containing compounds by intestinal bacteria. Therefore, Citation 2 cannot bring about the beneficial effect of the present invention.

As evidenced by the fact Citation 2 uses soluble and insoluble fibers in combination, this citation lacks a concept of exploiting the fiber with intestinal bacteria. Thus, the present invention can in no way be derived from Citation 2.

Accordingly the present invention set forth in main Claim 1 and dependent Claims 2-10 could not be accomplished from either or a combination of Citations 3-6.

(e) Conclusion

The applicant would ask for befitting examination of the application taking the foregoing assertions into account.

[Translation]

AMENDMENT
(Amendment under Article 19)

To: Hiroshi Ogawa, Commissioner of the Patent Office
(Yumiko Kawaguchi, Examiner of the Patent Office)

1. Identification of the International Application PCT/JP2004/004319

2. Applicant

Name: Cheiron Japan Co.

Address: 202, 25-1, Funabashi 3-chome, Setagaya-ku, Tokyo, 156-0055 Japan

Country of nationality: JAPAN

Country of residence: JAPAN

3. AGENT

Name: (8127) Yoshiharu Yoshida, Patent Attorney

Address: Shuwa No.2 Toranomom Building 6F, 21-19, Toranomom 1-chome,
Minato-ku, Tokyo, 105-0001 Japan

4. Item to be Amended: Claims

5. Subject Matter of Amendment

(1) Claim 1 is amended to "Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds, which contains, as basic ingredients, more than 5% by weight of water-soluble indigestible polysaccharides exploited by intestinal bacteria in terms of dried foodstuff and has restricted addition of protein components."

(2) Claim 2 is amended to "Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to Claim 1, wherein said food contains more than 5% by weight of indigestible polysaccharides in terms of dried foodstuff and protein components restricted to 8% or less by weight."

6. List of Attached Documents

(1) Replacing page 23 of claims

CLAIMS:

1. (Amended) Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds, which contains, as basic ingredients, more than 5% by weight of water-soluble indigestible polysaccharides exploited by intestinal bacteria in terms of dried foodstuff and has restricted addition of protein components.

2. (Amended) Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to Claim 1, wherein said food contains more than 5% by weight of indigestible polysaccharides in terms of dried foodstuff and protein components restricted to 8% or less by weight.

3. Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to claim 1 or claim 2, wherein said indigestible polysaccharides are one kind selected from pectine, polydextrose, alginic acid, fucoidan, chitin, chitosan, testa-derived hemicellulose, acacia gum, arum root-derived mannan, agar, and sugar alcohol and polymers of sugar alcohol.

4. Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to claim 2, wherein said indigestible polysaccharides contains at least polydextrose and pectine with a ratio of 0.05 to 100 parts by weight of pectine to 100 parts of polydextrose.

5. Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to any of claims 1, 2 and 4, further containing at least one of trace metal, vitamin and fat.

6. Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to claim 3, further containing at least one of trace metal, vitamin and fat.

7. Pathological improvement food for lowering blood concentration of low-molecular-weight nitrogen-containing compounds according to any of claims 1, 2 and 4, which food is formed in beverage, biscuit, cookie, cake, ice cream, sherbet, bread, noodle or jelly.